AMENDED IN ASSEMBLY APRIL 19, 2005 AMENDED IN ASSEMBLY APRIL 5, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL

No. 497

Introduced by Assembly Member Negrete McLeod

February 16, 2005

An act to amend Section—4161 4162.5 of the Business and Professions Code, relating to pharmacy practices.

LEGISLATIVE COUNSEL'S DIGEST

AB 497, as amended, Negrete McLeod. Drug wholesalers and manufacturers: licensure exemption. nonresident wholesaler license surety bond.

Existing law, the Pharmacy Law, provides for the licensure and regulation by the California State Board of Pharmacy of pharmacies and other persons. Under that law, a person located outside of this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state at wholesale is considered an out-of-state distributor that must be licensed by the board prior to engaging in those activities. Existing law, operative January 1, 2006, to January 1, 2011, requires an applicant for the issuance or renewal of a nonresident wholesaler license to submit a surety bond of \$100,000, or an equivalent means of security, for each site to be licensed by the nonresident wholesaler through which dangerous drugs or dangerous devices are to be shipped, mailed, or delivered to a site located in California.

This bill would-exempt from this licensure requirement certain transactions between affiliated or related wholesalers, as defined instead require a single \$100,000 surety bond, or an equivalent means

-2-**AB 497**

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of security, to be submitted by an applicant for the issuance or renewal of a nonresident wholesaler license.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 4161 of the Business and Professions 2 Code, as added by Chapter 887 of the Statutes of 2004, is 3 amended to read:

SECTION 1. Section 4162.5 of the Business and Professions Code is amended to read:

4162.5. (a) (1) An applicant for the issuance or renewal of a nonresident wholesaler license shall submit a surety bond of one hundred thousand dollars (\$100,000) for each site to be licensed, or other equivalent means of security acceptable to the board, such as an irrevocable letter of credit, or a deposit in a trust account or financial institution, payable to the Pharmacy Board Contingent Fund. The purpose of the surety bond is to secure payment of any administrative fine imposed by the board and any cost recovery ordered pursuant to Section 125.3.

- (2) For purpose of paragraph (1), the board may accept a surety bond less than one hundred thousand dollars (\$100,000) if the annual gross receipts of the previous tax year for the nonresident wholesaler is ten million dollars (\$10,000,000) or less in which the surety bond shall be twenty-five thousand dollars (\$25,000).
- (3) For applicants who satisfy paragraph (2), the board may require a bond up to one hundred thousand dollars (\$100,000) for any nonresident wholesaler who has been disciplined by any state or federal agency or has been issued an administrative fine pursuant to this chapter.
- (b) The board may make a claim against the bond if the licensee fails to pay a fine within 30 days of the issuance of the fine or when the costs become final.
- (c) A single surety bond or other equivalent means of security acceptable to the board shall satisfy the requirement of subdivision (a) for all licensed sites under common control as defined in Section 4126.5.

-3- AB 497

(d) This section shall become operative on January 1, 2006, and shall become inoperative and is repealed on, January 1, 2011, unless a later enacted statute, that is enacted before January 1, 2011, deletes or extends those dates.

- 4161. (a) A person located outside this state that ships, mails, or delivers dangerous drugs or dangerous devices into this state shall be considered a nonresident wholesaler.
- (b) A nonresident wholesaler shall be licensed by the board prior to shipping, mailing, or delivering dangerous drugs or dangerous devices to a site located in this state.
- (c) A separate license shall be required for each place of business owned or operated by a nonresident wholesaler from or through which dangerous drugs or dangerous devices are shipped, mailed, or delivered to a site located in this state. A license shall be renewed annually and shall not be transferable.
- (d) The following information shall be reported, in writing, to the board at the time of initial application for licensure by a nonresident wholesaler, on renewal of a nonresident wholesaler license, or within 30 days of a change in that information:
 - (1) Its agent for service of process in this state.
- (2) Its principal corporate officers, as specified by the board, if any.
 - (3) Its general partners, as specified by the board, if any.
- (4) Its owners if the applicant is not a corporation or partnership.
- (c) A report containing the information in subdivision (d) shall be made within 30 days of any change of ownership, office, corporate officer, or partner.
- (f) A nonresident wholesaler shall comply with all directions and requests for information from the regulatory or licensing agency of the state in which it is licensed, as well as with all requests for information made by the board.
- (g) A nonresident wholesaler shall maintain records of dangerous drugs and dangerous devices sold, traded, or transferred to persons in this state, so that the records are in a readily retrievable form.
- (h) A nonresident wholesaler shall at all times maintain a valid, unexpired license, permit, or registration to conduct the business of the wholesaler in compliance with the laws of the state in which it is a resident. An application for a nonresident

AB 497 — 4 —

wholesaler license in this state shall include a license verification from the licensing authority in the applicant's state of residence.

- (i) The board may not issue or renew a nonresident wholesaler license until the nonresident wholesaler identifies a designated representative-in-charge and notifies the board in writing of the identity and license number of the designated representative-in-charge.
- (j) The designated representative-in-charge shall be responsible for the nonresident wholesaler's compliance with state and federal laws governing wholesalers. A nonresident wholesaler shall identify and notify the board of a new designated representative-in-charge within 30 days of the date that the prior designated representative-in-charge ceases to be the designated representative-in-charge.
- (k) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be fixed by the board at an amount not to exceed the annual fee for renewal of a license to conduct business as a nonresident wholesaler.
- (1) The registration fee shall be the fee specified in subdivision (f) of Section 4400.
- (m) The licensure requirements of this section shall not apply to a nonresident wholesaler that ships, mails, or delivers dangerous drugs or dangerous devices solely to an affiliated or related wholesaler licensed by the board pursuant to Section 4160. For purposes of this subdivision, an affiliated or related wholesaler is one where the wholesaler shipping, mailing, or delivering the product and the wholesaler receiving the product are under common ownership and control of the same business entity.
- (n) This section shall become operative January 1, 2006.